

NIH SBIR Q&A for Conference Call

October 8, 2003

1. Has NIH considered a modular Phase I SBIR trial for the December 1 SBIR deadline? The pilot could include new and resubmissions of SBIR Phase I proposals. There would be only a few questions to ask (compared to the existing functionality).

Answer: No, this is not being considered right now. The first priority will be to include the feedback from the Pilot into a new release as soon as possible before the scope of the process is expanded.

2. Some costs are going into OtherDirectCosts and I'm not sure why. For instance:

There is an element in the RAR for EquipmentCosts and the crosswalk maps Equipment costs to it (**BudgetSummary . BudgetPeriod . Equipment**).

There is no element in the RAR for Supplies, so those costs go into **BudgetSummary . BudgetPeriod . OtherDirectCosts . Type=Supplies**.

Why, though, does the Crosswalk map Travel costs to **BudgetPeriod . OtherDirectCosts . Type=Travel** instead of to **BudgetPeriod . Travel**?

Answer: First, we need to assert that for the pilot, there should not be *any* amounts that need to be put into individual cost categories. By definition, a modular grant does not supply this information. So, while the question is valid, it does raise some cause for concern. If the question is being prompted by receipt of an application that includes this level of information, then it is likely that the intended submission is going to be rejected on the grounds that it violates our parameters for the pilot.

But, in answer to the question, the travel costs are mapped to an NIH-specific element because the RAR-defined component does not match our data collection on the 398 form. "BudgetPeriod. TravelCosts" provides the capability to identify multiple types of travel, broken down by foreign and domestic. We collect only the total so one of the types would have to be arbitrarily selected. That by itself would have been workable, but the key factor in the decision was that the RAR-defined component does not provide the ability to supply a descriptive text element to accompany the cost. A description is solicited for every budget category that is itemized on page 4 (including travel). The OtherDirectCosts component provides the appropriate model for this type of data capture, so we crosswalk to that element instead.

3. When we initially submitted the ticket, we received an error due to the fact that the "&" (ampersand) character was included in the project title and organization department data elements. We were able to resolve the issue and submit the ticket by editing this character to be the word "and." We have thoroughly searched the "List of Validations used by NIH for 398-based Modular grant application" document and we can't find a validation rule for characters such as the "&" (ampersand) in data elements.

Answer: Characters such as the ampersand are special characters in XML and must be encoded to be accepted in an XML element value (e.g., the & is encoded: &). See <http://www.w3.org/TR/REC-xml>.

Additional items and clarifications from the NIH development team

DUNS Number

- The DUNS number is a 9-digit **character** field with leading zeros.
- The DUNS number in the ticket envelope (ebXML) is the DUNS of the service provider sending the message.
- The DUNS number in the ticket payload (institutionID) is the DUNS of the institution submitting the application, not the service provider.

Commons Accounts

- PI and SO MUST BE registered in the Commons: No exceptions.
- Other Key Personnel with biosketches should have Commons accounts to maintain the integrity of the information.

Key Personnel: Issues and October Pilot guidelines

Background

The original intent of the Key Personnel section of the electronic application was to collect the primary investigators already known to the submitter, not future positions to be filled. The rule was that each Key Person must have a Commons user id. The User ID in the Commons uniquely identifies the person and allows:

- Attaching the biosketch information to the right person
- Obtaining information from the Commons profile for the application.
- Associating automatically the person to other information already in the eRA System

The practice in the paper world is to add key but unnamed *positions* on the grant and sometimes any personnel as key persons. Sometimes the Key Person section is used for the entire staffing plan, a practice that does not follow the NIH guidelines.

While NIH will revisit the entire issue of key personnel in the coming year, the CGAP project needs to make some adjustments immediately and for the intermediate range.

Immediately for the October- November Pilot

All key personnel must have a Commons Account. The Commons user ID of the investigator(s) must be used in the electronic system. Substituting the ID of the Signing Official will not work! If a Commons account cannot or should not be created, then that person or position should not appear under key personnel.

The staffing plan as a whole can be added as a text field in the budget justification section for Personnel. Since that section is free text, the entire staffing plan can be repeated, the key personnel can be marked as key.

The biosketches on key personnel with no Commons ID will be ignored and flagged as errors.

The NIH CGAP team and CSR will notify the NIH SRA to look for the complete staffing plan in the Budget Section and alert reviewers to make sure they find the right information. The electronic applications will be identifiable to the SRA and reviewers.

The application image generated by the NIH will reflect the information stored in the database and therefore may be slightly different from the paper application already submitted. If needed, duplicate copies of the paper application can be made for the SRA and reviewers.

Post-Pilot Solutions

Post Pilot structural changes will have to be made to address this issue. The development team has drafted some solutions but the policy arm of the NIH will have to review and provide guidelines. The only guarantee we have is that the October solution will change.

Most likely key personnel other than the PI will not be required to have a Commons account. An internal, local ID will be devised to tie the biosketches to key personnel in the schema. The key person and key positions with their related information will be loaded in different data structures than currently. The relationship between application Key Personnel data and Commons profiles will be specified.

A whole number of issues need to be considered when this change is made and will not be done this week. Specifications may not be available until after the Pilot.